



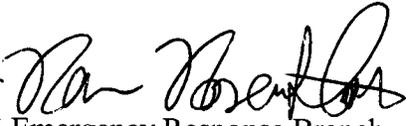
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

January 27, 2005

**ACTION MEMORANDUM**

**SUBJECT:** Inert Ingredient Tolerance Reassessment – Hydroxypropyl Guar Gum (CAS Reg. No. 39421-75-5)

**FROM:** Dan Rosenblatt, Chief   
Minor Use, Inerts, and Emergency Response Branch

**TO:** Lois A. Rossi, Director  
Registration Division

**I. FQPA REASSESSMENT ACTION**

**Action:** Reassessment of one (1) inert ingredient exemption from the requirement of a tolerance

**Chemical:** Hydroxypropyl Guar Gum (CAS Reg. No. 39421-75-5)

**Use Summary:** Hydroxypropyl guar gum is used as an inert ingredient as a thickener in pesticide formulations applied to growing crops only. Hydroxypropyl guar gum is used as an indirect food additive and as a sizing agent in textiles/papers. Hydroxypropyl guar gum and other similar substances are also widely used in oil field drilling applications.

**List Reclassification Determination:** Hydroxypropyl guar gum is classified as a List 3 inert. Based on the low risk finding, hydroxypropyl guar gum can be reclassified as a List 4A inert ingredient.

**II. MANAGEMENT CONCURRENCE**

I concur with the reassessment of the one (1) exemption from the requirement of a tolerance for the inert ingredient hydroxypropyl guar gum and with the List reclassification determination, as described above. I consider the one (1) exemption from the requirement of a tolerance for

hydroxypropyl guar gum established in 40 CFR §180.920 [formerly 40 CFR§180.1001(d)] to be reassessed as of the date of my signature, below. A Federal Register Notice regarding this tolerance exemption reassessment decision will be published in the near future.

*Lois A. Rossi*

Lois A. Rossi, Director  
Registration Division

Date: *February 7, 2005*

cc: Debbie Edwards, SRRD  
Joe Nevola, SRRD



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

January 27, 2005

**MEMORANDUM**

SUBJECT: Reassessment of the Exemption from the Requirement of a Tolerance for Hydroxypropyl Guar Gum

FROM: Kerry Leifer, Inerts Team Leader  
Minor Use, Inerts and Emergency Response Branch  
Registration Division (7505C)

A handwritten signature in black ink, appearing to read "Kerry Leifer", written over the typed name in the "FROM:" field.

TO: Dan Rosenblatt, Chief  
Minor Use, Inerts and Emergency Response Branch  
Registration Division (7505C)

**Background**

Attached is the Lower Risk Pesticide Chemical Focus Group's science assessment for hydroxypropyl guar gum. This assessment summarizes available information on the use, physical/chemical properties, toxicological effects, exposure profile, and environmental fate and ecotoxicity of hydroxypropyl guar gum. The purpose of this document is to reassess the existing exemption from the requirement of a tolerance for residues of hydroxypropyl guar gum as required under the Food Quality Protection Act (FQPA).

**Executive Summary**

This report evaluates hydroxypropyl guar gum (CAS Reg. No. 39421-75-5), a pesticide inert ingredient for which an exemption from the requirement of a tolerance exists for its residues when used in pesticide formulations applied to growing crops only under 40 CFR §180.920 [formerly 40 CFR §180.1001(d)].

Hydroxypropyl guar gum is a slightly modified form of guar gum. Guar gum is a high molecular weight carbohydrate polymer derived from the natural seed of the guar plant (*Cyamopsis tetragonolobus*). Guar gum is a direct food additive primarily used as a thickening agent that has been affirmed as generally recognized as safe (GRAS) by the FDA. In a previous Focus Group decision document, guar gum was among a number of natural carbohydrate polymers that were determined to be low toxicity substances and for which the exemptions from the requirement of a tolerance for their uses as inert ingredients in pesticides could be reassessed. Another Focus Group decision document for cellulose and cellulose derivatives included a determination that the hydroxypropyl derivatives of cellulose and of methyl cellulose were low toxicity substances for which tolerance exemptions could be established as minimal risk inert/active ingredients.

The tolerance exemption for hydroxypropyl guar gum being reassessed in this document is found under 40 CFR §180.920 [formerly 40 CFR §180.1001(d)] and is for the use of hydroxypropyl guar gum as an inert ingredient in pesticide formulations applied to growing crops only. The listed use under that tolerance exemption is as a thickener. Hydroxypropyl guar gum is also used as an indirect food additive and as a sizing agent in textiles/papers. Hydroxypropyl guar gum and other similar substances also find wide used in oil field applications.

Taking into consideration all available information on hydroxy guar gum, including the fact that it is a high molecular weight polymeric polysaccharide that is not absorbed by any route of exposure, it has been determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to hydroxypropyl guar gum when considering dietary exposure and all other nonoccupational sources of pesticide exposure for which there is reliable information. Therefore, it is recommended that the exemptions from the requirement of a tolerance established for residues of hydroxypropyl guar gum in/on raw agricultural commodities be considered reassessed as safe under section 408(q) of the FFDC .

## **I. Introduction**

This report evaluates hydroxypropyl guar gum (CAS Reg. No. 39421-75-5), a pesticide inert ingredient for which an exemption from the requirement of a tolerance exists for its residues when used in pesticide formulations applied to growing crops only under 40 CFR §180.920 [formerly 40 CFR §180.1001(d)].

Hydroxypropyl guar gum is a slightly modified form of guar gum. Guar gum is a high molecular weight carbohydrate polymer derived from the natural seed of the guar plant (*Cyamopsis tetragonolobus*). Guar gum is a direct food additive primarily used as a thickening agent that has been affirmed as generally recognized as safe (GRAS) by the FDA (21 CFR 184.1339). In a previous Focus Group decision document, guar gum was among a number of natural carbohydrate polymers that were determined to be low toxicity substances and for which the exemptions from the requirement of a tolerance for their uses as inert ingredients in

pesticides could be reassessed (EPA 2002a). Another Focus Group decision document for cellulose and cellulose derivatives included a determination that the hydroxypropyl derivatives of cellulose and of methyl cellulose were low toxicity substances for which tolerance exemptions could be established. (EPA 2002b)

Guar gum's polymeric structure contains numerous hydroxyl groups, which can be treated to form propylene glycol ethers, resulting in hydroxypropyl guar gum. As is the case with the hydroxypropyl derivatives of cellulose and methylcellulose, this modification has an impact upon the viscosifying properties of the polymer (which makes it more desirable for certain commercial applications) but does not increase toxicological concerns.

## **II. Use Information**

The tolerance exemption for hydroxypropyl guar gum being reassessed in this document is found under 40 CFR §180.920 [formerly 40 CFR §180.1001(d)] and is for the use of hydroxypropyl guar gum as an inert ingredient in pesticide formulations applied to growing crops only. The listed use under that tolerance exemption is as a thickener.

### **Other Uses**

Hydroxypropyl guar gum is used as an indirect food additive and as a sizing agent in textiles/papers. Hydroxypropyl guar gum and other similar substances are widely used in oil field applications in both fracture fluids and in drilling muds as they exhibit rapid viscosity development, excellent electrolyte resistance, good thermal stability and good shear dilutability.

## **III. Hazard Assessment**

The Agency conducted an extensive literature search including TOXNET databases (HSDB, IRIS, CCRIS, GENE-TOX, TOXLINE, and DART/ETIC). There are no available data specifically related to the toxicity of hydroxypropyl guar gum to animals or humans.

Like guar gum, cellulose and the cellulose derivatives that have previously been assessed by the Focus Group, hydroxypropyl guar gum is a high molecular weight polymer that is devoid of reactive functional groups and which is not absorbed by any route of human exposure. Hydroxypropyl guar gum is a water-absorbing polymer, and as is the case with water absorbing polymers, there are potential concerns related to lung effects resulting from inhalation exposures to particles of the neat material. However, this concern was previously addressed in conjunction with guar gum and the other plant product thickeners in the April 8, 2002, Focus Group decision document which stated, "*These chemicals have been identified as posing moderate concern for human health through the inhalation route if the particle size is sufficiently small to be inhaled into deep lungs (< 10 microns), and if the substance is sufficiently present in the formulation. However, in their use as thickeners in pesticide formulations, they will have already absorbed*

*water and "swelled" to a larger particle size, and will therefore not be of toxicological concern through an inhalation route."*

#### SAR Assessment Performed by OPPT

A structure activity review (SAR) assessment was performed by EPA's Office of Pollution Prevention and Toxics (OPPT) in December 2004 (EPA 2004). Absorption is nil from all routes as a high molecular weight material. A submission under section 8(e) of the Toxic Substances Control Act (TSCA) for an unknown molecular weight form of hydroxypropyl guar gum indicated that the substance tested positive in a Ames bacterial assay for mutagenicity. Another TSCA section 8(e) submission reported some possible evidence of dermal and respiratory sensitivity for workers exposed to guar dust. Hydroxypropyl guar gum was judged to be of moderate concern for human health based on the two TSCA section 8(e) reports and lung effects resulting from inhalation exposures as discussed above.

#### **Special Considerations for Infants and Children**

At this time, there is no concern for potential sensitivity to infants and children. A safety factor analysis has not been used to assess the risk. For these same reasons the additional tenfold safety factor is unnecessary.

#### **IV. Exposure Assessment**

Since hydroxypropyl guar gum can be considered to be a low toxicity polymer, there is no reason to expect that use of hydroxypropyl guar gum will constitute any significant hazard. Therefore, a quantitative screening-level exposure assessment has not been conducted.

#### **V. Risk Characterization**

Hydroxypropyl guar gum is slightly modified form of guar gum, which is an affirmed GRAS substance that has been concluded to be a low toxicity substance. Based on its close structural relationship to guar gum, as well as its high molecular weight and inability to be absorbed via any route of exposure, hydroxypropyl guar gum is a polymer which can also be considered to be a low toxicity substance. Taking into consideration all available information on hydroxypropyl guar gum, it has been determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to hydroxypropyl guar gum when considering dietary exposure and all other nonoccupational sources of pesticide exposure for which there is reliable information. Therefore, it is recommended that the exemption from the requirement of a tolerance established for residues of hydroxypropyl guar gum in/on raw agricultural commodities be considered reassessed as safe under section 408(q) of the FFDCR

## **VI. Environmental Fate/Ecotoxicity/Drinking Water Considerations**

### *Environmental Fate Characterization*

As a high molecular weight polysaccharide biopolymer, hydroxypropyl guar gum is readily biodegradable with microbial degradation being the major route of transformation in the environment. Adsorption onto soil and sediment particulates is very strong and, therefore, there is negligible potential to reach surface water by dissolved runoff and/or leach to ground water (EPA 2004). Volatilization from soils and water is not likely to be a transport process in the environment. The potential to bioaccumulate is expected to be very low.

### *Ecotoxicity and Ecological Risk Characterization*

Hydroxypropyl guar gum, based on its high molecular weight and polysaccharide structure, would be expected to be of low acute and chronic toxicity to fish (fathead minnow), invertebrates (*Daphnia magna*) and green algae (*Selenastrum capricornutum*) (EPA 2004). Similarly, based on the high molecular weight and nonbioavailability of this substance, toxicity to terrestrial organisms is expected to be low. Overall, use of this substance as a pesticide inert ingredient would be of negligible ecological concern.

## **VII. Aggregate Exposures**

In examining aggregate exposure, FFDCa section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

For hydroxypropyl guar gum, a qualitative assessment for all pathways of human exposure (food, drinking water, and residential) is appropriate given its low toxicity.

## **VIII. Cumulative Exposure**

Section 408(b)(2)(D)(v) of the FFDCa requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Hydroxypropyl guar gum is a low toxicity chemical. Therefore, the resultant risks separately and/or combined should also be low.

EPA does not have, at this time, available data to determine whether hydroxypropyl guar gum has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to hydroxypropyl guar gum and any other substances and this material does not appear to produce a toxic metabolite produced by

other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that hydroxypropyl guar gum has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

**References:**

TOXNET 2004. Hazardous Substance Data Bank (HSDB). On-line Scientific Search Engine, National Library of Medicine, National Institute of Health. <http://www.toxnet.nlm.nih.gov>.  
Search terms: Hydroxypropyl guar gum

U.S. Environmental Protection Agency (EPA) 2002a. IIFG Decision Memo. Memorandum from K. Boyle and K. Leifer to F. Forrest. May 29, 2002.

U.S. Environmental Protection Agency (EPA) 2002b. January 8, 2002 Meeting of the IIFG Decision Memo. Memorandum from K. Boyle and K. Leifer to F. Forrest. April 8, 2002.

U.S. Environmental Protection Agency (EPA) 2004. Structure Activity Team Report: Guar gum, 2-hydroxypropyl ether. Office of Pollution Prevention and Toxics. December 7, 2004.